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### **REMARKS**

This Supplemental Preliminary Amendment is being submitted at the request of Supervisory Patent Examiner Amy Nelson and puts the claims in form for allowance pursuant to the telephone call of September 2, 2003 and per the meeting of supervisory and primary Examiners on September 11, 2003. The present application relates to inbred maize line PH54M. Claims 2-72 have been canceled. Claims 17-20, 30-33, 36, and 44-46 were previously canceled in the Preliminary Amendment of July 17, 2003 and claims 30-32, and 44-46 were previously canceled in the Amendment of January 6, 2003. New claims 73-102 have been added. No new matter has been added by the present amendment. Applicant respectfully requests consideration of the following remarks.

#### **Detailed Action**

##### ***A. Claim and Specification Objections***

Applicant acknowledges the objection to claims 8 and 27 as withdrawn. The rejection of claims 1-49 under 35 U.S.C. § 112, second paragraph are acknowledged as withdrawn in light of the previous claim amendments. Applicant also acknowledges the rejection of claims 1-49 under 35 U.S.C. § 112, first paragraph as withdrawn, in light of the deposit. Applicant further acknowledges the rejection of claims 18-20 and 47-49 under 35 U.S.C. § 112, first paragraph is withdrawn in light of the previous claim amendments.

##### ***B. Claim Objections***

The Examiner objects to claims 51 and 53 due to the article "The" in line 1 should be --A--. Applicant has now canceled claims 51 and 53, thereby obviating this objection.

##### ***C. Newly Submitted Claims***

Applicant acknowledges the addition of new claims 73 through 102, as specifically stated by the claims faxed by Examiner David Fox on November 15, 2002 and the new sample claim submitted by Supervisory Patent Examiner Amy Nelson via e-mail on August 7, 2003 and August 25, 2003 and September 2, 2003 and per the meeting of supervisory and primary Examiners on September 11, 2003. The new claims do not add new matter as there is support for the claims in the originally filed specification. Support for the specific items noted in the claims faxed by Examiner Fox can be found within the specification for *Bacillus thuringiensis* on page 28; for imidazolinone, sulfonylurea, glyphosate, glufosinate, L-phosphinothricin, triazine, and

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benzonitrile on pages 31-32; for phytase on page 32; for stearyl-ACP desaturase, fructosyltransferase, levansucrase, alpha-amylase, invertase and starch branching enzyme on pages 32-33; and for waxy starch and increased amylose starch on pages 21 and 33. For the reasons aforementioned, it is respectfully submitted that Applicant's claims are sufficiently described and enabled by the specification. In addition, Applicant has amended the specification to clarify the deposit language. No new matter has been added by the present amendment. Entry of this Supplemental Preliminary Amendment and approval of the changes is respectfully requested.

**Rejections under 35 U.S.C. § 112, Second Paragraph**

Claims 22, 33, 47-49, and 50-53 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

Claim 22 is indefinite for the recitation "said plant has essentially the same morphology and physiology of inbred maize line PH54M other than the trait of male sterility." The Examiner states it is unclear what is meant by "essentially the same".

Applicant has canceled claim 22, thus alleviating this rejection.

The Examiner rejects claim 33 for the recitation "pedigree of said PH54M-progeny maize plant is within 2 or less crosses" as being indefinite.

Applicant has now canceled claim 33, thereby alleviating this rejection.

Claim 47 is indefinite for the recitation "essentially unchanged" as the Examiner states it is not clear what is "unchanged".

Applicant has canceled claim 47, alleviating this rejection.

The Examiner rejects claim 50 for the claim broadens the scope of the claims from which it depends.

Although not acceding to the Examiner's rejection, Applicant has now canceled claim 50, thus alleviating this rejection.

Claims 51-53 are indefinite for the recitation "inbred PH54M maize plant conferring a backcrossed trait". The Examiner states it is not clear what is meant by a plant that confers a backcrossed trait.

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Applicant respectfully traverses this rejection. The specification clearly states that "[o]ne or more genes may be introduced using these techniques. Desired traits transferred through this process include, but are not limited to, waxy starch, nutritional enhancements, industrial enhancements, disease resistance, insect resistance, herbicide resistance and yield enhancements. The gene of interest is transferred from the donor parent to the recurrent parent, in this case, the maize plant disclosed herein." See page 21, lines 16-31; see also page 4 lines 5-19. However, in order to expedite prosecution, Applicant has canceled claims 51-53, thereby rendering this rejection moot.

The Examiner rejects claim 52 as for attempting to limit the "inbred PH54M maize plant conferring a backcrossed trait of claim 51" when claim 51 is directed to a method. Claim 52 is also indefinite for the recitation "essentially the same traits".

Applicant has canceled claim 52, thus alleviating these rejections.

In light of the above amendments and remarks, Applicant respectfully requests reconsideration and withdrawal of the rejections under 35 U.S.C. § 112, second paragraph.

#### **Rejections Under 35 U.S.C. § 112, First Paragraph**

Claims 9-20, 28, 29, 33-39, 41-43, and 47-49 remain rejected and claims 22 and 50-53 stand rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for the reasons of record stated in the Office Action mailed September 4, 2002.

The Applicant traverses the rejection. Although not acceding to the Examiner's rejection, to expedite prosecution the Applicant has canceled claims 9-20, 22, 28, 29, 33-39, 41-43, 47-49 and 50-53, thereby rendering this rejection moot. The Applicant has added new claims 73-102, as specifically stated by the claims faxed by Examiner David Fox on November 15, 2002 and the new sample claim submitted by Supervisory Patent Examiner Amy Nelson via e-mail on August 7, 2003 and revised via telephone on August 25, 2003 and September 2, 2003 and per the meeting of supervisory and primary Examiners on September 11, 2003. The new claims do not add new matter as there is support for the claims in the originally filed specification as described *supra*.

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In addition, Applicant asserts that the introgression of mutant genes and transgenes is easily, routinely and extensively practiced by those of ordinary skill in the art. Backcrossing has been known since the 1920's and, because of its predictability, is the method preferred by commercial plant breeders to introduce transgenes into already developed and tested material. An example of how one of ordinary skill in the art can transfer a gene conferring a qualitative trait into a variety through backcrossing is demonstrated by the fact that the commercial market now distributes a multitude of products produced in this manner. Such conversion lines are easily developed without undue experimentation.

Further, the Applicant would like to reiterate that a patent application "need not teach, and preferably omits, what is well known in the art." *Hybritech Inc. v. Monoclonal Antibodies Inc.*, 802 F.2d 1367, 231 U.S.P.Q. 81 (Fed. Cir. 1986); MPEP § 601.

It is understood by those of skill in the art that backcross conversions are routinely produced and do not represent a substantial change to a variety. The World Seed Organization, on its web site, writes, "The concept of an essentially derived variety was introduced into the 1991 Act of the UPOV Convention in order to avoid plagiarism through mutation, multiple backcrossing and to fill the gap between Plant Breeder's Rights and patents." As determined by the UPOV Convention, "essentially derived varieties may be obtained for example by the selection of a natural or induced mutant, or of a somaclonal variant, the selection of a variant individual from plants of the initial variety, backcrossing, or transformation by genetic engineering.

In light of the above amendments and remarks, Applicant respectfully requests reconsideration and withdrawal of the rejections to claims 9-20, 22, 28, 29, 33-39, 41-43, 47-49 and 50-53 under 35 U.S.C. § 112, first paragraph.

#### **Issues Under 35 U.S.C. § 102/103**

Claims 9, 10, 13, 14, 17, 22, 28, 29, 33, 36, 41-43, 47-49 remain and claim 52 stand rejected under 35 U.S.C. § 102(b) as anticipated by or, in the alternative, under 35 U.S.C. § 103(a) as obvious over Loisel *et al.* (U.S. Patent No. 5,986,185). The Examiner asserts this rejection is repeated for the reasons of record as set forth in the last Office Action mailed September 4, 2002.

Applicant has canceled claims 9, 10, 13, 14, 17, 22, 28, 29, 33, 36, 41-43, 47-49 and 52, thereby alleviating this rejection. Applicant acknowledges the addition of new claims 73 through

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102, as specifically stated by the claims faxed by Examiner David Fox on November 15, 2002 and the new sample claim submitted by Supervisory Patent Examiner Amy Nelson via e-mail on August 7, 2003 and August 25, 2003 and September 2, 2003 and per the meeting of supervisory and primary Examiners on September 11, 2003. The new claims do not add new matter as there is support for the claims in the originally filed specification. Further, Applicant submits *In re Thorpe*, states that "a product by process claim may be properly rejected over prior art teaching the same product produced by a different process", as noted by the Examiner. *In re Thorpe*, 227 U.S.P.Q. 964, 966 (Fed. Cir. 1985). However, Applicant submits that this is not the same product physiologically or morphologically as the cited prior art as can be evidenced by one skilled in the art through analysis of the data tables in each. In addition, it is impermissible to use hindsight reconstruction and the benefit of Applicant's disclosure to pick among pieces which are present in the art; there must be some suggestion to make the combination and an expectation of success. *In re Vaeck*, 20 U.S.P.Q.2d 1434 (Fed. Cir. 1991). Moreover, Applicant claims a method of making a plant which did not previously exist. Pursuant to the recent Federal Circuit decision, *Elan Pharmaceuticals, Inc. v. Mayo Foundation for Medical Education & Research*, 304 F.3d 1221, (Fed. Cir. 2002), "a novel patented product is not 'anticipated' if it did not previously exist." *Id.* This is the case whether or not the process for making the new product is generally known. *Id.*

In light of the above, Applicant respectfully requests that the Examiner reconsider and withdraw the rejections to claims 9, 10, 13, 14, 17, 22, 28, 29, 33, 36, 41-43, 47-49 and 52 under 35 U.S.C. § 102(b) as anticipated by or, in the alternative, under 35 U.S.C. § 103(a) as obvious over *Loisel et al.* (U.S. Patent No. 5,986,185).

#### Summary

Applicant acknowledges that claims 1-8, 21, 23-27, and 40 are allowed.

Applicant has amended the claims as suggested by Examiner David Fox and Supervisory Patent Examiner Amy Nelson as allowable. Applicant submits the claims place the application in condition for allowance and comply with all requirements of form set forth in previous office actions.

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**Conclusion**

In conclusion, Applicant submits in light of the above amendments and remarks, the claims as amended are in a condition for allowance, and reconsideration is respectfully requested. If it is felt that it would aid in prosecution, the Examiner is invited to contact the undersigned at the number indicated to discuss any outstanding issues.

No fees or extensions of time are believed to be due in connection with this amendment; however, consider this a request for any extension inadvertently omitted, and charge any additional fees to Deposit Account No. 26-0084.

Reconsideration and allowance is respectfully requested.

Respectfully submitted,



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